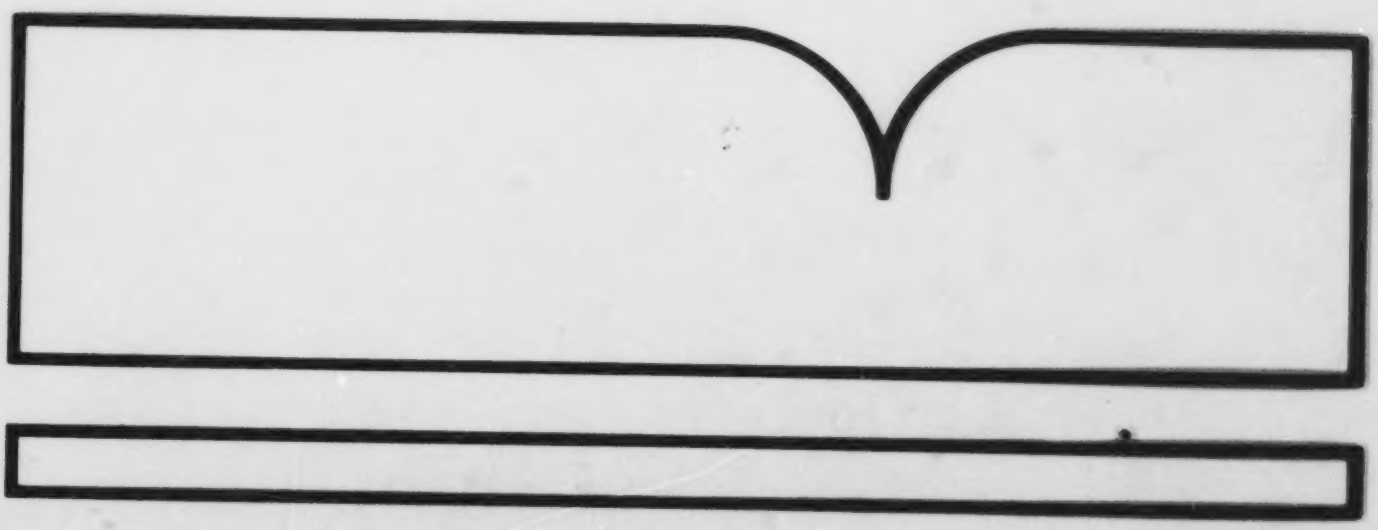
PB89-164198

# Guidance for the Reregistration of Pesticide Products Containing 'Bacillus thuringiensis' as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Dec 88



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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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# Guidance for the Reregistration of Pesticide Products Containing *Bacillus thuringiensis* as the Active Ingredient

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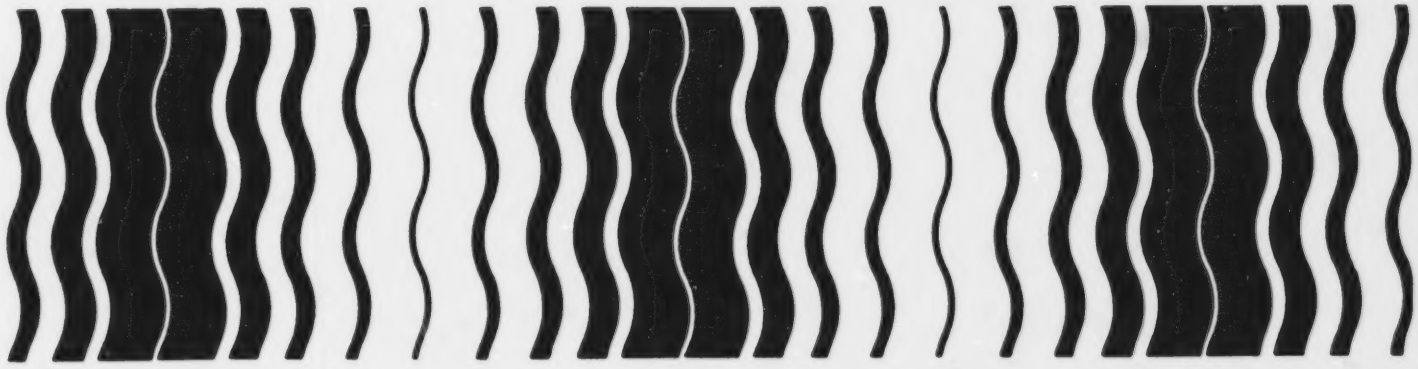

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# REGISTRATION STANDARD

# FOR THE

# REREGISTRATION OF PESTICIDE PRODUCTS

# CONTAINING

# *Bacillus thuringiensis*

# AS THE ACTIVE INGREDIENT

CASE NUMBER 0247

OPP Chemical Codes: 006401, 006402, 006403, 006405, and 128946

DECEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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## GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| ADI | Acceptable Daily Intake. Also known as the Reference Dose or RfD. |
| a.i. | active ingredient |
| ARC | Anticipated Residue Contribution |
| CAS | Chemical Abstracts Service |
| CSF | Confidential Statement of Formula |
| EEC | Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem. |
| EP | End Use Product |
| EPA | U.S. Environmental Protection Agency |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| LC50 | Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm. |
| LD50 | Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is usually expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LEL | Lowest Effect Level |
| MPI | Maximum Permissible Intake |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency. |
| MP | Manufacturing Use Product |
| NPDES | National Pollutant Discharge Elimination System |
| NOEL | No Observed Effect Level |
| OPP | Office of Pesticide Programs |

| | |
|---|---|
| PADI | Provisional Acceptable Daily Intake |
| ppm | parts per million |
| RfD | Reference Dose |
| TMRC | Theoretical Maximal Residue Contribution |

## I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a

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[1]The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket, Field Operations Division, by calling (703) 557-2805 or by writing EPA, Public Information Branch, FOD, 401 M Street, S.W., Washington, DC 20460.

regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV- Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify

the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is

independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

## II. MICROBIAL PESTICIDES COVERED BY THIS STANDARD

### A. DESCRIPTION OF MICROBIAL PESTICIDES

This Standard covers microbial pesticides containing the microorganism *Bacillus thuringiensis* as described in Volume 2 of *Bergey's Manual of Systematic Bacteriology*, 1986 edition, and in section IV.A. of this Registration Standard.

Identifying nomenclature and codes of currently registered subspecies are shown below. (Although the Agency and industry have used the term "variety" in the past, the correct taxonomic designation is "subspecies.")

| | |
|---|---|
| Microbial Pesticide Name:<br>OPP Chemical Code: 006401 | *Bacillus thuringiensis* (all subspecies) |
| Microbial Pesticide Name:<br>OPP Chemical Code: 006401 | *Bacillus thuringiensis* subsp. *israelensis* |
| Microbial Pesticide Name:<br>OPP Chemical Code: 006402 | *Bacillus thuringiensis* subsp. *kurstaki* |
| Microbial Pesticide Name:<br>OPP Chemical Code:006403 | *Bacillus thuringiensis* subsp. *aizawai* |
| Microbial Pesticide Name:<br>OPP Chemical Code: 128946 | *Bacillus thuringiensis* subsp. *san diego* |
| Microbial Pesticide Name:<br>OPP Chemical Code: 006405 | *Bacillus thuringiensis* subsp. *tenebrionis* |

## B. USE PROFILE

Type of Pesticide: Microbial

Mode of Action: Insect toxicity

Target Pests: Bacillus thuringiensis subsp. israelensis: mosquito (larvae), fungus gnats (larvae), and black flies (larvae);
B.t. subsp. aizawai: Greater wax moth (larvae);
B.t. subsp. kurstaki: Lepidopterous larvae
B.t. subsp. san diego: Colorado potato beetle (larvae) and elm leaf beetle (larvae and adults)

Registered Uses:

| | |
|---|---|
| B.t. subsp. israelensis: | Terrestrial food crop use on pastures; |
| | Aquatic food crop use on rice; |
| MPs - 4<br>EPs - 30<br>24(c)s - 1 | Aquatic nonfood crop use on brackish water, mangrove swamps, salt marshes, tidal water, drainage systems, irrigation systems, flood water areas, woodland pools, standing water, polluted water, sewage waste lagoons, ponds, lakes, and streams; |
| | Greenhouse nonfood crop use on ornamental plants; |
| | Domestic outdoor use on standing water around the dwellings. |
| B.t. subsp. aizawai: | Indoor use on empty honeycombs. |
| EPs - 1 | |
| B.t. subsp. kurstaki: | Terrestrial food crop uses on cotton, corn, soybeans, |
| MPs - 7<br>EPs - 161<br>24(c)s - 56 | sorghum (grain crop), small grains, hops, fruits (banana, blueberry, caneberries, |

cranberry, currant, citrus fruits, grapes, kiwi fruit, pome fruits, stone fruits, small fruits, strawberry, tropical fruits, vegetables (artichoke, asparagus, avocado, beans, beets, carrots, celery, cole crops, cucumber, dandelion, eggplant, endive, lentils, lettuce, melons, okra, onions, parsley, parsnip, peas, pepper, potato, pumpkin, radish, rutabaga, safflower, spinach, squash, sugar beets, sugar maple, sunflower, sweet potato, Swiss chard, ti, tomato, watercress, watermelon), nuts (nut crops, nut trees, peanut, walnut), flavoring and spice crops, garlic, horseradish, mint, salisfy, and forage crops, alfalfa, hayage, pastures and rangelands;

Terrestrial nonfood crop uses on tobacco, ornamental flowering and herbaceous plants, ornamental and/or shade trees, and ornamental turf;

Aquatic food crop use on rice and wild rice;

Greenhouse food crop uses on beans, beets, carrots, celery, cole crops, cucumber, eggplant, endive, flavoring and spice crops, garlic, lentils, lettuce, melons, onions, parsley, peas, peppers, potato, radish, spinach, squash, sweet potato, strawberry, tomato.

Greenhouse nonfood crop uses on agricultural research crops and ornamental flowering, herbaceous and woody plants;

Forestry uses on forest trees;

Indoor uses on stored birdseed; herbs, spices, and condiments; grain crops; peanuts; agricultural and oil seeds; soybeans, sunflower, and tobacco (including flue-cured).

B.t. subsp. san diego: Terrestrial food crop uses on eggplant, potato and tomato; Terrestrial nonfood crop uses on elm trees.

EPs - 1

B.t. subsp. tenebrionis: Terrestrial food crop use on potatoes.

EPs - 1

Methods of Application: Hand sprayer; water treatment by aerial or ground equipment; soil application by drip or overhead irrigation systems; foliar application by aerial, conventional ground or hand-held equipment and center-pivot irrigation systems; sprayer or sprinkler cans.

Rates of Application: B.t. subsp. israelensis:
Terrestrial food crop - 0.14 to 1.82 billion AA*IU*/A
Aquatic food crop - 0.14 to 1.82 billion AA IU/A
Aquatic nonfood crop - 0.14 to 2.54 billion AA IU/A
0.001 to 0.04 billion AA IU/100 sq ft
3,785 to 409,600 AA IU/gal treated water
Greenhouse nonfood crop-0.31 to 2.42 billion AA IU/100 gal
Domestic outdoor - 0.001 to 0.004 billion AA IU/100 sq ft

B.t. subsp. kurstaki:
Terrestrial food crop - 0.73 to 29.04 billion IU*/A
Terrestrial nonfood crop-0.125 to 24.0 billion IU/A
1.67 to 4.06 billion IU/5,000 sq ft
Greenhouse food crop - 0.10 to 1.01 billion IU/2,500 sq ft
Greenhouse nonfood crop-0.20 to 0.3 billion IU/2,500 sq ft
Forestry - 0.125 to 24.0 billion IU/A
Indoor - 7.26 to 27.25 billion IU/1,000 sq ft
27.23 to 65.6 billion IU/1,000 bushels

B.t. subsp. aizawai:
Indoor - 0.003 billion GM* IU/frame

B.t. subsp. san diego:
Terrestrial food crop - 44.5 to 133.5 billion CBP*IU/A
Terrestrial nonfood crop-89 to 178 billion CPB IU/100 gal

B.t. subsp. tenebrionis:
Terrestrial food crop - 12.6 to 18 billion tenebrionis units/A

Formulations: Technicals, formulation intermediate, dusts, granular, pelleted/tablet, wettable powder, emulsifiable concentrate, flowable concentrate, ready-to-use, and pressurized liquid.

Basic Producers: Bacillus thuringiensis subsp. israelensis

- Abbott Laboratories, Chicago, IL
- Duphar B.V., Weesp, Holland
- Novo Industri AS, Copenhagen, Denmark
- Zoecon Corporation, A Sandoz Company Dallas, Texas

Bacillus thuringiensis subsp. kurstaki

- Abbott Laboratories, Chicago, IL
- Duphar B.V., Weesp, Holland
- Novo Industri AS, Copenhagen, Denmark
- Sandoz Crop Protection Corp., Des Plaines, IL
- Ecogen, Inc., Langhorne, PA

Bacillus thuringiensis subsp. aizawai

- Sandoz Crop Protection Corp., Des Plaines, IL

Bacillus thuringiensis subsp. san diego

- Mycogen Corporation, San Diego, CA

Bacillus thuringiensis subsp. tenebrionis

- Sandoz Crop Protection Corp., Des Plaines, IL

Year of Intitial Registration: 1961

* AA = Aedes aegypti
IU = International Units
GM = Galleria mellonella
CPB = Colorado potato beetle

## III. AGENCY ASSESSMENT

The Agency reviewed and evaluated available data, including both data submitted to the Agency in support of registration of B. thuringiensis as an active ingredient and data from the published literature. This information served as the basis for issuance of a draft Registration Standard in 1986. On October 10, 1986, the Agency informed the public regarding the availability of the draft Registration Standard for comment in the FEDERAL REGISTER, 51 FR 37488. In the comment period of two months, five commenters responded to the Agency. All comments have been taken into consideration in the issuance of this final Registration Standard. The specific comments, as well as the Agency's responses, are present in the public docket assigned to this Registration Standard.

In the 1986 draft Registration Standard, the Agency concluded that adequate data were available to assess the toxicological and other biological effects of B. thuringiensis on mammals, that no data gaps existed in the toxicology data base, and that there were no substantial human or environmental safety concerns except for certain endangered lepidopteran insect species. Although substantial gaps were found to exist in the ecological effects data base, there were no substantive concerns regarding unreasonable adverse effects of B. thuringiensis for the registered products. Therefore, the Agency concluded that the use of B. thuringiensis products could be continued, and that products could be used as registered, with only minor precautionary labeling changes and additional nontarget organism data being required.

Since the issuance of the 1986 draft Registration Standard, the Agency has revised the Pesticide Assessment Guidelines Subdivision M, reassessed endangered species hazard, and reviewed additional data on B. thuringiensis. The Agency has also more keenly focused on product identity; i.e., strain-to-strain variability within subspecies designations. Current methods applicable to strain identification have advanced considerably since the initial B. thuringiensis registration (1961). As with conventional chemical products, it is essential to know product identity so that the applicability of test results, i.e. toxicity testing and host range, can be related to specific products. A major focus of this Registration Standard is to obtain state-of-the-art identification data on B. thuringiensis strains. Each registered strain must be placed in a recognized culture collection and is subject to the data requirements of this Standard.

Although the data submitted to the Agency since 1986 show rodent and nontarget organism effects, these data do not change the assessment of the draft 1986 Registration Standard that there is no evidence of any substantial human or environmental safety concerns related to current uses of B. thuringiensis.

A. Identity of the "Active Ingredient" (Strain/Subspecies)

Currently, the Agency groups B. thuringiensis active ingredients according to the subspecies designation of the strain (i.e., all strains of one subspecies are one active ingredient). There were 3 active ingredients registered prior to the 1986 draft Registration Standard (subspecies kurstaki, israelensis, and aizawai) and two more have been registered since then (subspecies san diego and tenebrionis).

Taxonomic classification of subspecies (and therefore designation of active ingredient) is based almost entirely upon flagellar antigen serotyping. Serotype designation is not necessarily indicative of pesticidal activity. Therefore, the current system classifies active ingredients in a manner that does not necessarily have a bearing on the actual active ingredient (e.g., insecticidal toxins). In fact, delta endotoxin genes are resident on plasmids and can be transferred among B. thuringiensis strains, potentially changing toxin production without changing the flagellar antigen serotype.

Therefore, the Agency no longer recognizes flagellar antigen serotyping as sufficient by itself to classify strains for pesticide regulatory purposes. Instead, the Agency will classify strains based on the identification data required by this Registration Standard, including biochemical and morphological data, flagellar antigen serotype analysis, strain history, antibiotic resistance patterns, description of the insecticidal toxins produced, plasmid profiles, morphological description of crystalline proteins, bioassays for insect host range, and the mouse intraperitoneal toxicity/pathogenicity screen.

Strain variability is a phenomenon that further complicates the regulation of B. thuringiensis products and the use of data derived from the testing of one strain to support conclusions drawn concerning another strain. The Agency defines a B. thuringiensis strain as being made up of descendants of a single isolate in pure culture that are essentially the same as the original isolate with respect to the characterization data being required by this Registration Standard. Strains originally registered with the Agency have, in all probability, become modified or been replaced so that it is possible that data supporting the registration of the original strain may not be sufficient to support the strain currently in the registered pesticide product. The Agency will use the characterization data, further described in the Regulatory Position and Rationale and in the Data Tables, to more accurately reclassify the different strains of B. thuringiensis into distinct active ingredients.

B. Mode of Activity

B. thuringiensis's pesticidal effects are attributable primarily to protein toxins. The best known of these are the lepidopteran and dipteran active P1 or delta endotoxin and the dipteran active P2 endotoxin. These protoxins are apparently solubilized in the alkaline midgut of the lepidopteran and dipteran larvae. The protoxin is then enzymatically digested to the active toxin which damages the midgut lining and allows midgut material to diffuse into the hemolymph with consequent elevated pH and paralysis of the insect.

B. thuringiensis strains also produce toxins that are active against other insects. However, the presence of these toxins in B. thuringiensis pesticide products is not fully known. Therefore, this Standard requires the submission of data to determine the presence of these toxins.

C. Human/Mammalian Health Effects

B. thuringiensis was one of the first insect pathogens registered in the United States and was required to undergo what, at the time, was a rigorous toxicity/infectivity evaluation. Much of the original testing for B. thuringiensis was based on the testing requirements for conventional chemical pesticides. In 1986 when the draft Registration Standard was issued, there were no significant human health concerns and no mammalian toxicity/ infectivity data gaps for B. thuringiensis. Many studies conducted prior to the issuance of the 1986 draft were conducted using several routes of administration in rats, mice, rabbits, and guinea pigs. These data indicate that if there are any deleterious effects caused by the use of products containing B. thuringiensis, they are very minimal. Most of the data are on B. thuringiensis subspecies kurstaki and israelensis. These studies were conducted before EPA issued testing guidelines and hence lack uniformity in reporting of dose levels (e.g. # spores/animal, grams of spores/body weight or grams of spores/animal). Thus, a comparative assessment is impossible.

Data submitted subsequent to the 1986 draft Registration Standard shows acute toxicity when very high levels of certain B. thuringiensis strains are administered to test rodents via the pulmonary/and or intravenous routes. The Agency is uncertain whether the adverse effects observed in rodents after acute pulmonary exposure or acute intravenous exposure to high levels of B. thuringiensis are relevant to other larger mammals including humans. When the data required by this

Registration Standard are received and reviewed, the Agency should be able to better assess risks to human health from registered strains of B. thuringiensis and to determine the applicability of these data to each registered strain. In order to determine the significance of the effects observed at high dose levels in rodents, the Agency currently is investigating (via cooperative agreement with IIT Research Institute) nonspecific toxic effects related to particle size, particle number, and to differential toxicities related to pulmonary and intravenous exposures.

The Agency has received no reports of adverse pulmonary or intravenous effects in exposed humans related to current uses of B. thuringiensis.

D. Ecological Characteristics

Prior to the 1986 draft Registration Standard, the Agency reviewed numerous ecological effect studies submitted in support of the registration of B. thuringiensis products, as well as studies in the open literature, to assess the potential risks to nontarget organisms posed by the registered uses of B. thuringiensis. In general, the data indicated no adverse effects on nontarget insects, birds, and mammals. The applicability of these data will be determined once the characterization data are submitted on each registered strain.

1. Aquatic Organisms - Data Submitted Prior to the 1986 Draft Registration Standard

Few toxic effects have been reported in studies on B. thuringiensis exposure to aquatic species. A study conducted with an end use product containing 3.2% B. thuringiensis subspecies kurstaki, with a potency of 16,000 IUs per milligram of product, suggests possible toxicity to mussels and brine shrimp. This was a static tank test in which the test organism were subjected to various doses of this product for 96 hours. The highest dose tested with mussels (400 ppm) showed 28 percent mortality; the highest dose tested with brine shrimp showed 90 percent mortality. The $LC_{50}$ for shrimp was calculated at 85 mg/L (85 ppm). However, it could not be determined whether the reported mortalities were the results of toxic effects of the microbial pesticide or due to other factors. Hence, the data are considered inconclusive.

2. Invertebrates - Data Submitted Prior to the 1986 Draft Registration Standard

Studies of populations of nontarget terrestrial invertebrate organisms following applications of B. thuringiensis to fields have not revealed significant adverse

effects on nontarget invertebrates. In field tests in Nova Scotia, where B. thuringiensis was the only insecticide applied to an apple orchard over a 4-year period, population levels of Lepidopteran target insects were reduced, but there was no reported effect on beneficial predacious insects.

High concentrations of B. thuringiensis subspecies kurstaki spores have been found to be toxic to bees and earthworms; however, toxicity only occurred at concentrations greater than those expected with normal pesticide application.

3. Data Submitted After the 1986 Draft Registration Standard

Since the 1986 draft Registration Standard was written, data have been submitted which show acute toxicity in birds (178 ppm $LD_{50}$ and 1 ppm NOEL) and suggest adverse effects in freshwater fish, plants, aquatic invertebrates, and rare beneficial insects. The contribution of inert ingredients to toxicity as well as the relevance to environmental risk of routes of exposure and dose levels used in testing have yet to be determined. Therefore, whether these results show hazard to nontarget organisms in the environment cannot be determined until additional data are submitted.

4. Endangered Species

Risk to federally listed endangered species cannot be fully determined at this time. However, the U.S. Fish and Wildlife Service (FWS) has determined (1987) that certain uses of the subspecies kurstaki jeopardize the continued existence of the Kern primrose sphinx moth, Lange's metalmark butterfly, Smith's blue butterfly, El Segundo blue butterfly, Oregon silverspot butterfly, San Bruno elfin butterfly, Lotis blue butterfly, and the Schaus swallowtail butterfly. An earlier consultation (1984) with FWS addressing rangeland/pastureland pesticide use found that B. thuringiensis (subspecies not specified) jeopardize the existence of the Kern Primrose Sphinx moth, Delta Green Ground Beetle, and the Valley Elderberry Longhorn Beetle. As some B. thuringiensis products have activity against dipterans, these products could effect any endangered dipterans that may be listed in the future.

5. Tolerance Reassessment

An exemption from the requirement of a tolerance has been established for the viable spores of B. thuringiensis on raw agricultural commodities (RACs) under the provisions of 40 CFR 180.1011. The Agency has determined that all products and uses covered by this Registration Standard must abide by the provisions of the tolerance exemption, including nonfood use products. The tolerance exemption regulation requires that the

microbial insecticide for which exemption from the requirement of a tolerance is established shall have the following specifications:

a. The microorganism shall be an authentic strain of B. thuringiensis Berliner conforming to the morphological and biochemical characteristics of B. thuringiensis as described in Bergey's Manual of Determinative Bacteriology, Eighth Edition.

b. Spore preparations of B. thuringiensis shall be produced by pure culture fermentation procedures with adequate control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.

c. Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of five laboratory test mice weighing 17 to 23 g. Such tests shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.

d. Spore preparations shall be free of B. thuringiensis beta-exotoxin when tested with the fly larvae toxicity test ("Microbial Control of Insects and Mites," R.P.M. Bond et al., p 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a B. thuringiensis strain which does not produce beta-exotoxin under standard manufacturing conditions or by periodically determining that beta-exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.

The exemption from the requirement of a tolerance is established under 40 CFR 180.1011 for residues of the microbial insecticide B. thuringiensis in or on beeswax and honey, and all other RACs when B. thuringiensis is applied either to growing crops, or when applied after harvest, in accordance with good agricultural practices.

The 40 CFR 180,1011 tolerance exemption for B. thuringiensis is currently being reevaluated by the Agency. This reevaluation will continue as data submitted in response to the Registration Standard are reviewed. Areas which the Agency wishes to address in this reevaluation include the scope of the exemption (e.g. whether asporogenic strains should be included), quality assurance measures, limits or restriction on the presence of beta-exotoxin and whether or not the mouse subcutaneous test should be replaced with a mouse intraperitoneal test.

The 40 CFR 180.1001(c) inert tolerance exemption for B. thuringiensis fermentation solids and/or solubles is also currently being reevaluated by the Agency as product analysis data are submitted in response to the Registration Standard.

## IV. REGULATORY POSITION AND RATIONALE

### A. REGULATORY POSITIONS AND RATIONALES

1. The Agency is requiring a specific set of tests designed to better characterize registered strains of Bacillus thuringiensis. The Agency defines a B. thuringiensis strain as being made up of descendants of a single isolate in pure culture which are essentially the same as the original isolate when characterized by the data being required by this Registration Standard. The Agency will use these data to reclassify registered strains into groups of strains with similar characteristics. These new groupings, based upon the characterization data required by this Registration Standard, will form the basis for active ingredient designation of B. thuringiensis products.

   Rationale - The Agency's current practice of grouping B. thuringiensis active ingredients by subspecies is not sufficiently specific to insure that all products within a group have substantially similar pesticidal characteristics. The taxonomic subspecies (Although the Agency and industry have used the term "variety" in the past, the correct taxonomic designation is "subspecies.") designation for B. thuringiensis is based largely upon the flagellar antigen serotyping of the subject strain. Many insecticidal toxin-producing genes are resident in plasmids and, therefore, may be exchanged between different subspecies of B. thuringiensis as well as certain other Gram-positive bacteria and may not alter the flagellar antigens. Because changes in activity and host range may not be reflected by changes in the flagellar antigens, flagellar serotyping is an inadequate method in and of itself for regulatory purposes.

2. The following nine characterization data are required for each B. thuringiensis strain currently registered. Refer to Appendix I, Tables A and B for further information.

   a. Standard biochemical and morphological testing for B. thuringiensis, as specified in the 1986 edition of Bergey's Manual of Systematic Bacteriology and subsequent additions.

b. Flagellar antigen serotype analysis, as described by de Barjac.

c. History of the strain.

d. Standard, Gram-positive, antibiotic susceptibility patterns.

e. Description of insecticidal toxins produced.

f. Plasmid profiles.

g. Morphological description of crystalline proteins.

h. Bioassays for insect host range.

i. Mouse intraperitoneal toxicity/pathogenicity screen.

Rationale - The flagellar antigen serotype designation of de Barjac is not adequate by itself to clearly identify and group different B. thuringiensis strains for regulatory purposes. The above characterization data will allow the Agency to better classify the strains of B. thuringiensis that are present in registered products. In addition, these data will provide the Agency with information to allow for a more accurate determination of whether or not data can be shared between closely related strains of B. thuringiensis.

3. Each distinct strain, including each strain within a subspecies, is subject to all the data requirements applicable to the use pattern(s) of that strain. In order to utilize data submitted to the Agency prior to the issuance of this Registration Standard, registrants must show that the strain used in testing is substantially similar to the strain present in the product currently.

Rationale - Due to the current Agency grouping of B. thuringiensis by subspecies and the variability of strains within a subspecies, data supporting one strain within a subspecies may not be adequate to support another strain in the same subspecies.

4. Each registrant must establish the number of B. thuringiensis strains present in their product based upon the characterization data detailed in the paragraph 2 above. If more than one strain is present, then each strain will be subject to the requirements set forth in this Registration Standard.

Rationale - Testing performed on one of the B. thuringiensis strains present in a particular product may not adequately describe the properties of any other B. thuringiensis strain present.

5. A pure culture of each B. thuringiensis strain to be registered is to be deposited in a recognized national or international culture collection. Within 12 months, each registrant must identify for the Agency which culture collection has been chosen as a strain depository. Also, batch-to-batch genetic variation is to be minimized by use of seed derived from aliquots of a large initial batch of the strain on which the mammalian and environmental studies were conducted. Registrants should periodically test subsequent aliquot producing batches, grown from an aliquot of the original aliquot producing batch, to assure that strain variation has not taken place. Such variation would include change in host range, quantity (unrelated to culture conditions) and types of toxins produced, etc.

   Rationale - The above requirement will help assure that B. thuringiensis strains in commerce do not change over time or, if they do, that the Agency has adequate data to characterize any such change.

6. Based upon data submitted in response to this Registration Standard, the Agency intends to reevaluate the current tolerance exemption for B. thuringiensis in Section 180.1011 of Title 40 of the Code of Federal Regulations (40 CFR 180.1011) and the inert tolerance exemption for B. thuringiensis fermentation solids and/or solubles in 40 CFR 180.1001(c)

   Rationale - Questions regarding potential hazards (such as possible human pathogen or toxin contaminants) cannot be reevaluated until data required by the Standard have been submitted and reviewed.

7. The batch-to-batch testing requirements currently set forth for food use B. thuringiensis products, in 40 CFR 180.1011, will be required of nonfood use B. thuringiensis products, such as those intended for forestry use.

   Rationale - Analysis for production batch contaminating microorganisms and their metabolites is not currently required of nonfood use products, such as those used in forestry programs. In order to assure public and applicator safety, the Agency believes such testing requirements need to be imposed on all B. thuringiensis products.

8. The amount of active ingredient must be determined by a specific and quantitative assay for the insecticidal toxins present in the product and be expressed as a percentage of the total product weight. The Agency hereby rescinds PR Notice 71-6, which set the requirement for determining percent active ingredient based on the potency of the spore preparation.

   Rationale - The toxins that B. thuringiensis produces are the primary factor contributing to insect toxicity. The percent of active ingredient is thus best quantified by determining the amount of these toxins present in the product.

9. This standard will cover all naturally occurring strains of B. thuringiensis as well as those strains that have been altered via plasmid curing and/or intraspecies transconjugation. Strains altered in a manner other than described here will be registered on a case by case basis in accordance with the Agency's evolving policies and procedures. Organisms other than B. thuringiensis that have been engineered to contain genes from B. thuringiensis will not be covered by this Registration Standard.

   Rationale - The Agency considers such genetically engineered pesticidal products to have the potential to be sufficiently different to warrant testing and risk assessment on a case-by-case basis.

10. The Agency is not requiring data on ground water.

    Rationale - There is no evidence that B. thuringiensis poses a health risk via the oral route of exposure. Hence, there is no evidence to raise a ground water concern. Furthermore, B. thuringiensis exists in the soil under natural conditions throughout the world.

11. Risk to federally listed endangered species from the use of B. thuringiensis cannot be fully determined at this time. However, the U.S. Fish and Wildlife Service (FWS) has determined (1987) that certain uses of the subspecies kurstaki may jeopardize the continued existence of the Kern primrose sphinx moth, Lange's metalmark butterfly, Oregon silverspot butterfly, Mission blue butterfly, San Bruno elfin butterfly, Lotis blue butterfly, and the Schaus swallowtail butterfly. In addition, a 1984 Biological Opinion from the Fish and Wildlife Service on potential threats to endangered species from pesticides used on range and pastureland declares that B. thuringiensis (subspecies

unspecified) jeopardize the continued existance of of the Kern Primrose Sphinx moth, Delta Green Ground Beetle, and the Valley Elderberry Longhorn Beetle.

EPA is developing a program to reduce or eliminate exposure to endangered species to a point where pesticide use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed.

As explained below, labeling requirements issued in PR Notices 87-4 and 87-5 have been withdrawn pending re-issuance.

Pending the receipt of data required by this Registration Standard, the Agency will reinitiate consultation with FWS regarding the all registered subspecies of B. thuringiensis in regard to endangered species hazard. (This consultation will also clarify which endangered insects may be jeopardized by specific strains of B. thuringiensis.)

No additional labeling is being required at this time.

Rationale - Until the characterization data required by this Registration Standard are received and reviewed by the Agency, the presence of atypical insecticidal toxins present in B. thuringiensis subspecies cannot be determined, i.e. a coleopteran active toxin present in a kurstaki strain. Data to be called in by this Standard will enable us to better define the nontarget host range of B. thuringiensis subspecies registered. At that time, the Agency will submit a request to the Fish and Wildlife Service for a revised Biological Opinion on B. thuringiensis subspecies.

In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to FWS findings that certain pesticides, including Bacillus thuringiensis jeopardized the continued existance of endangered species. These PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988 the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending the development of a more focused program to protect endangered species.

EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

12. The Agency will not place B. thuringiensis into Special Review at this time.

    Rationale - Based on the data available to the Agency, B. thuringiensis does not meet or exceed any of the risk criteria specified in 40 CFR 154.7 for Special Review.

13. The Agency will not restrict the use of B. thuringiensis products to certified applicators.

    Rationale - There is no indication that B. thuringiensis meets the criteria for restricted use at this time.

14. The characterization data of the product analysis data requirements will be given priority review.

    Rationale - The characterization data are necessary to determine the applicability of all other data submitted to support the registration of subject strains.

15. The Agency is not requiring a reentry interval for B. thuringiensis.

    Rationale - There are no reported toxicological effects under current use patterns that warrent establishment of a reentry interval at this time. This issue will be reevaluated after receipt of the data requested in this Registration Standard.

16. The Agency will not at this time require protective clothing for all B. thuringiensis products.

    Rationale - The issue of requirements for protective clothing will be considered as a generic issue for all

microbial pesticides and will be addressed at a later date.

17. End-use product storage stability data will be required specifically to determine the presence or absence of beta-exotoxin.

    Rationale - The Agency is concerned that beta-exotoxin may be formed in some end use products subsequent to formulation and that the provisions of 40 CFR 180.1011 may not adequately prevent the presence of beta-exotoxin in food use B. thuringiensis pesticide products.

18. Continuation of Registration - While data gaps are being filled, currently registered manufacturing-use products and end-use products containing B. thuringiensis as the active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide, or agree to develop, additional data, as specified in the Data Appendices, in order to avoid suspension of existing registrations.

    Rationale - Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency may choose not to cancel or withhold registration if data are missing or are inadequate (see FIFRA sections 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for obtaining necessary data. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

## B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain B. thuringiensis, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

## C. ACCEPTABLE RANGES AND LIMITS

### 1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain B. thuringiensis. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1% for chemicals.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing B. thuringiensis provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products must be labeled for formulation into end-use products only for the sites/uses listed in the EPA Compendium of Acceptable Uses.

D. LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing B. thuringiensis may be released for shipment by the registrant after December 30, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing B. thuringiensis may be distributed or sold after December 30, 1991 unless the product bears an amended label which complies with the requirements of this Standard.

The Agency is permitting a 2 and 3 year compliance timeframe for labeling to allow for the submisssion and evaluation of the characterization data and analytical methodology on which labeling depends. The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredient Statement

Under the general labeling requirements of 40 CFR 156.10, every registered pesticide must have an ingredient statement on its approved label listing the active ingredient(s) and the corresponding percentages of each active ingredient so declared. Pesticide Registration (PR) Notice 71-6, dated April 9, 1971, required all preparations of Bt registered by the Agency to

declare active ingredient percentage based upon units of potency. The Agency is rescinding PR Notice 71-6 and is requiring that active ingredient declarations be based upon percent by weight of insecticidal toxin(s) present determined by analytical methods. Strain variety, as well as percent active ingredient declared for each order of insects affected must appear on the label. Although the Agency is rescinding PR Notice 71-6, potency units may still appear on the label at the registrant's option. In cases where registrants include potency, potency should appear below the ingredient statement and be followed by the statement "Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section."

A sample ingredient statement is listed below.

Active Ingredients:

Bacillus thuringiensis subspecies kurstaki

| | |
|---|---|
| Lepidopteran active toxin(s) . . . | 2% |
| Coleopteran active toxin(s) . . . | 1% |
| Dipteran active toxin(s) . . . . | 1% |
| Inert Ingredients: . . . . . | 96% |

Potency: 50,000 International Units per milligram of product or _____ billion International Units per pound/quart of this product. Potency units should not be used to adjust use rates beyond those specified in the Directions for Use section.

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in the EPA Compendium of Acceptable Uses. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Environmental Hazard Statements

The following revised environmental hazard statement must appear on all MP labels:

> Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

The following environmental hazard statement must appear on EP labels:

> Outdoor Use
> Do not contaminate water when disposing of equipment washwaters.

In addition, EPs that have the following outdoor uses must bear the corresponding labeling below:

> Forestry Use
> Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Aerial application over such sites is permissible only when they are not visible from above the tree canopy. Do not contaminate water when disposing of equipment washwaters.

> Direct Water Application
>
> Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles.

Uses Other Than Forestry and Direct Water Application

Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.

## V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

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[2]Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

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[3]If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

## VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the regis-tration of products containing this active ingredient.[4]

### A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

### B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to

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[4]Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. <u>What generic data must be submitted?</u>

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. <u>How to comply with DCI requirements</u>.

Within 90 days of your receipt of this Registration

Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when

the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

a. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Develop-ment of Data" (EPA Form 8580-6, enclosed).

b. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA sec. 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide

products in determining that a data require-ment applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the revised Pesticide Assessment Guidelines Subdivision M, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The revised Pesticide Assessment Guidelines Subdivision M, which is referenced in the Data Tables, will shortly be available at the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650). In the interim, copies may be obtained from the Public Information Branch of the Field Operations Division (TS-787C) within OPP.

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are

less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including

the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

## VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

## VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

## IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: *Bacillus thuringiensis* Registration Standard

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 12 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 12 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 12 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 12 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

# I. DATA APPENDICES

## GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the revised Pesticide Assessment Guidelines Subdivision M, which will shortly be available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161. In the interim, copies may be obtained from the Public information Branch of the Field Operations Division (TS-787C) within OPP.

2. Test Substance (Column 2).This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are generally those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLES A AND B

GENERIC AND MANUFACTURING USE PRODUCT DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS

| Guideline Citations and Name of Tests For Microbial Pesticides | | Test Substance 1/ | Use Patterns | Does EPA Have Data? 2/ | Bibliographic Citation 2/ | Must Additional Data be Submitted? 2/ | Timeframe for Submission |
|---|---|---|---|---|---|---|---|
| §158.170(a) | Product Analysis for Microbial Pesticides | | | | | | |
| 151A-10 | Product Identity | TGAI/MP | All | NO | N/A | Yes 3/ | 12 months |
| 151A-11 | Manufacturing process | " | " | NO | N/A | Yes | 12 months |
| 151A-12 | Discussion of formation of unintentional ingredients | " | " | NO | N/A | Yes 4/ | 12 months |
| 151A-13 | Analysis of samples | " | " | NO | N/A | Yes 5/ | 12 months |
| 151A-15 | Certification of limits | MP | " | NO | N/A | Yes | 12 months |
| 151A-15 | Analytical methods | " | " | NO | N/A | Yes | 12 months |
| 151A-16 | Physical and Chemical Properties: | | | | | | |
| | Color | TGAI/MP | " | NO | N/A | Yes | 12 months |
| | Physical state | " | " | NO | N/A | Yes | 12 months |
| | Odor | " | " | NO | N/A | Yes | 12 months |
| | Density or specific gravity | " | " | NO | N/A | Yes | 12 months |
| | pH | " | " | NO | N/A | Yes | 12 months |
| | Stability | TGAI | " | NO | N/A | Yes | 12 months |
| | Storage stability | TGAI/MP | " | NO | N/A | Yes 6/ | 15 months |
| | Viscosity | MP | " | NO | N/A | Yes 7/ | 12 months |
| | Miscibility | " | " | NO | N/A | Yes 8/ | 12 months |
| | Corrosion characteristics | " | " | NO | N/A | Yes 9/ | 15 months |
| 151A-17 | Submittal of sample | TGAI | " | NO | N/A | Yes 10/ | 12 months |
| -- | Special Testing | TGAI | " | NO | N/A | Yes 11/ | N/A 10/ |

1/ A separate study must be conducted on each test substance identified.

2/ Although product analysis data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

3/ To more adequately identify each strain in each test substance, the following characterization data are particularly important aspects of 151A-10. Data is to be developed on each B. thuringiensis strain present in the TGAI, except in the case of 3(h) and 3(i) for which the TGAI is the preferable test substance. References are provided as examples of appropriate procedures; it is possible that other validated procedures would be appropriate also.

a.) Standard biochemical and morphological testing for Bt as specified in the Volume 2 of Bergey's Manual of Systematic Bacteriology, 1986 and subsequent editions. Care should be taken to follow media preparation and testing procedures exactly as they appear in Bergey's Manual of Systematic Bacteriology so that testing is reproducible.

b.) Flagellar antigen serotyping as described by de Barjac in the following references.

- de Barjac, H. (1981) Identification of H-serotypes of Bacillus thuringiensis, pp. 35-43. In H.W. Burges (ed.) Microbial control of pest and plant diseases, 1970-1980. Academic Press, London.

- de Barjac, H.; Bonnefor, A (1973) Classification of Bacillus thuringiensis. Entomophaga 18:5-17.

c.) History of the strain including the following.

1. Previous codes or synonyms used to describe the strain.
2. How long the strain has been used in the subject pesticide product.
3. Description of any known changes to have occurred to the strain, i.e., changes that fall under any of the other characterization data. Intentional strain improvements are to be noted.
4. Storage history of the strain including media used to store and grow the strain.

d.) Standard Gram-positive antibiotic sensitivity patterns using the Kirby-Bauer disc diffusion method as decribed in the American Society for Microbiology's Manual of Clinical Microbiology.

e.) Insecticidal toxins produced.

f.) Plasmid profiles performed according to the following reference.

- Gonzalez, J.M., Jr.; Carlton, B.C. (1980) Patterns of plasmid DNA in crystalliferous and acrystalliferous strains of Bacillus thuringiensis. Plasmid 3:92-98.

g.) Description of crystalline proteins.

h.) Data showing which of the following insect orders are affected by the strain.

1) Lepidoptera;
2) Diptera;
3) Hymenoptera;
4) Coleoptera;
5) Orthoptera; and
6) Trichoptera.

i.) A screen for evaluating the pathogenicity and toxicity of the technical grade of the active ingredient of each currently registered strain of B. thuringiensis is to be done. In general, for the screen, mice (5 male and 5 females/dose level) are to be injected with a technical grade preparation of active ingredient containing $10^6$, $10^7$, and $10^8$ units of each B. thuringiensis strain present. All animals are to be observed frequently during the first day of dosing, and then daily for at least 6 additional days. Animal mortality and time of death after dosing, and nature, time of onset, and time to disappearance of all clinical signs of toxicity and illness are to be recorded.

These data are required for each strain in the technical product. Each time a strain is replaced, modified, or a variant selected, the Agency must be notified via an application for formulation amendment. At a minimum, the characterization data must be submitted for modified strains or selected variants. Unplannned variation is to be minimized by use of seed derived from aliquots of a large initial batch of the strain on which the human and environmental studies were conducted. Registrants should periodically test subsequent aliquot producing batches, grown from an aliquot of the original aliquot producing batch, to assure that strain variation has not taken place. Such variation would include change in host range, quantity (unrelated to culture conditions) and types of toxins produced, etc.

4/ This discussion should include the potential for alteration of the active strain(s) during fermentation or seed aliquot production via such processes as transconjugation by contaminating B. thuringiensis strains (perhaps present as carry-over from an earlier batch) or other species. If the potential exists, a quality control step should be introduced to monitor such changes.

5/ The insecticidal toxins produced by each strain are to be quantified via an analytical method such as SDS-polyacrylamide gel electrophoresis (SDS-PAGE), enzyme-linked immunosorbent assay (ELISA), or high pressure liquid chromatography (HPLC) for the purpose of reporting percent active ingredient on the CSF and the label.

6/ The storage stability study must include, but not be limited to, the detection of beta-exotoxin during storage of the MP.

7/ Required for liquid formulations only.

8/ Required for emulsifiable liquid formulations only.

9/ Required only when packaged in metal, plastic, or paper containers.

10/ A pure culture of each strain currently marketed (or soon to be marketed) must be deposited in a recognized culture collection. If a strain is modified, it will be considered a new strain and must be redeposited. Registrants will be notified in the event an Agency-approved/operated culture collection is selected for deposit of strains. Registrants are required to submit verification of which culture collection the strain is deposited in.

11/ Each production batch of the TGAI must be screened for the presence of pathogenic organisms using acceptable microbiological techniques. In addition, all other requirements of 40 CFR 180.1011 are to be performed on each production batch of the TGAI for all B. thuringiensis products, nonfood uses as well as food uses. These data are not to be submitted to the Agency, but must be made available to the Agency upon request. Registrants must notify the Agency of the presence of human pathogens immediately upon discovery under Section 6(a)(2) of FIFRA. Approval must be granted by the Agency before pathogen contaminated batches may be marketed.

TABLE A

GENERIC DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS

| Guideline Citations and Name of Tests For Microbial Pesticides | | Test Substance | Use Patterns | Does EPA 1/ Have Data? | Bibliographic 2/ Citation | Must Additional Data be Submitted? | Timeframe for Submission |
|---|---|---|---|---|---|---|---|
| §158.170(c) Toxiocology 3/ | | | | | | | |
| 152A-10 | Acute oral tox/path | TGAI | All | --- | --- | Yes | 12 months 4/ |
| 152A-12 | Acute pulmonary tox/path | TGAI | " | --- | --- | Yes | 12 months 4/ |
| 152A-13 | Acute intravenous tox/path | TGAI | " | --- | --- | Yes | 12 months 4/ |
| 152A-15 | Hypersensitivity incidents | ---- | " | --- | --- | Yes | 12 months 4/ |

1/ Until the Agency can determine that the strain of Bacillus thuringiensis used in testing is sufficiently similar to the strain currently used in the registered pesticide product, the Agency reserves judgement on whether or not data on file is acceptable.

2/ Bibliographic citations are reserved until studies are confirmed as acceptable.

3/ EPA has revised its data requirements for toxicology testing for microbial pesticides to reflect the scientific advances made in testing methodology, to focus more clearly on the microbial component of the product, and to reflect EPA's experience in regulating these microbial pesticides.

4/ The data that are required must be submitted within the timeframe indicated in the data table. However, if a company wishes to share data between different strains or wishes to utilize data already submitted to the Agency, then the timeframe for submissions will begin once the Agency has determined whether sharing of data is warranted or whether testing performed prior to this Registration Standard was done on strains similar enough to strains currently in registered pesticide products.

TABLE A

GENERIC DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS

| Guideline Citations and Name of Tests For Microbial Pesticides | | Test Substance | Use 1/ Patterns | Does EPA 2/ Have Data? | Bibliographic 3/ Citation | Must Additional Data be Submitted? | Timeframe for Submission |
|---|---|---|---|---|---|---|---|
| §158.170(d) Nontarget Organisms: For Microbial Pesticides | | | | | | | |
| Avian and Mammalian Testing | | | | | | | |
| 154A-16 | Avian oral | TGAI | A/B/C/D/G/H | --- | --- | Yes | 12 months 5/ |
| 154A-17 | Avian respiratory pathogenicity | " | " | --- | --- | Yes | 12 months 5/ |
| 154A-18 | Wild mammal | " | " | --- | --- | No | --- |
| 154A-25 | Terrestrial wildlife & aquatic organism | " | " | --- | --- | Reserved 4/ | --- |
| 154A-26 | Avian pathogenicity/ reproduction test | " | " | --- | --- | Reserved 4/ | --- |
| 154A-33 | Simulated & actual field tests- birds & mammals | " | " | --- | --- | No | --- |
| Aquatic Organism Testing | | | | | | | |
| 154A-19 | Freshwater fish | TGAI | A/B/C/D/G/H | --- | --- | Yes | 12 months 5/ |
| 154A-20 | Freshwater aquatic invertebrate | " | " | --- | --- | Yes | 12 months 5/ |
| 154A-21 | Estuarine & marine animal | " | " | --- | --- | Yes | 15 months 5/ |

1/ Because of the minimal exposure on nontarget species to Bacillus thuringiensis via Indoor and Greenhouse use patterns, the Agency has determined that nontarget organism testing for these use patterns is not required.

2/ Until the Agency can determine that the strain of B. thuringiensis used in testing is sufficiently similar to the strain currently used in the registered pesticide product, the Agency reserves judgement on whether or not data on file is acceptable

3/ Bibliographic citations are reserved until studies are confirmed as acceptable.

4/ Requirement reserved pending results of Tier I testing.

5/ The data that are required must be submitted within the timeframe indicated in the data table. However, if a company wishes to share data between different strains or wishes to utilize data already submitted to the Agency, then the timeframe for submissions will begin once the Agency has determined whether sharing of data is warranted or whether testing performed prior to this Registration Standard was done on strains similar enough to strains currently in registered pesticide products.

TABLE A

GENERIC DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS

| Guideline Citations and Name of Tests For Microbial Pesticides | Test Substance | Use 1/ Patterns | Does EPA 2/ Have Data? | Bibliographic 3/ Citation | Must Additional Data be Submitted? | Timeframe for Submission |
|---|---|---|---|---|---|---|
| §158.170(d) Nontarget Organisms: For Microbial Pesticides cont'd | | | | | | |
| Aquatic Organism Testing cont'd | | | | | | |
| 154A-25 Terrestrial wildlife & aquatic organism | TGAI | A/B/C/D/G/H | --- | --- | Reserved 4/ | --- |
| 154A-27 Definitive aquatic animal | " | " | --- | --- | Reserved 4/ | --- |
| 154A-28 Aquatic embryo & life cycle | " | " | --- | --- | Reserved 4/ | --- |
| 154A-29 Aquatic ecosystem | " | " | --- | --- | Reserved 4/ | --- |
| 154A-34 Simulated & actual field tests-aquatic organisms | TEP | " | --- | --- | Reserved 4/ | --- |
| Nontarget Plant Testing | | | | | | |
| 154A-22 Plant studies | TEP | " | --- | --- | Yes | 12 months 5/ |
| Nontarget Insect Testing | | | | | | |
| 154A-23 Nontarget insects | TGAI | " | --- | --- | Yes | 12 months 5/ |
| 154A-24 Honeybee testing | " | " | --- | --- | Yes | 12 months 5/ |

1/ Because of the minimal exposure on nontarget species to B. thuringiensis via Indoor and Greenhouse use patterns, the Agency has determined that nontarget organism testing for these use patterns is not required.

2/ Until the Agency can determine that the strain of B. thuringiensis used in testing is sufficiently similar to the strain currently used in the registered pesticide product, the Agency reserves judgement on whether or not data on file is acceptable.

3/ Bibliographic citations are reserved until studies are confirmed as acceptable.

4/ Requirement reserved pending results of Tier I testing.

5/ The data that are required must be submitted within the timeframe indicated in the data table. However, if a company wishes to share data between different strains or wishes to utilize data already submitted to the Agency, then the timeframe for submissions will begin once the Agency has determined whether sharing of data is warranted or whether testing performed prior to this Registration Standard was done on strains similar enough to strains currently in registered pesticide products.

TABLE A

GENERIC DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS

| Guideline Citations and Name of Tests For Microbial Pesticides | Test Substance | Use Patterns | Does EPA Have Data? | Bibliographic Citation | Must Additional Data be Submitted? | Timeframe for Submission |
|---|---|---|---|---|---|---|
| §158.170(b) Microbial Pesticide Residue Analysis 1/ | | | | | Reserved 1/ | |

1/ Residue data requirements apply when Tier II or Tier III toxicology data are triggered by the acute oral, acute pulmonary, or acute intravenous studies as required in the Toxicology Table A of this Registration Standard. See the revised Subdivision M for details concerning what results trigger Tier II or Tier III testing.

TABLE A

GENERIC DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS

| Guideline Citations and Name of Tests For Microbial Pesticides | Test Substance | Use Patterns | Does EPA Have Data? | Bibliographic Citation | Must Additional Data be Submitted? | Timeframe for Submission |
|---|---|---|---|---|---|---|
| §158.170(d) Environmental Fate for Microbial Pesticides 1/ | | | | | Reserved 1/ | |

1/ Environmental Fate data requirements apply when Tier II or Tier III testing is triggered by the results of Tier I testing required in the Nontarget Organism Table A of this Registration Standard. See revised Pesticide Assessment Guidelines Subdivision M for details concerning what results trigger Tier II or Tier III testing.

TABLE C

END USE PRODUCT DATA REQUIREMENTS FOR BACILLUS THURINGIENSIS[1]

| Guideline Citations and Name of Tests For Microbial Pesticides | Test Substance | Use Patterns | Does EPA Have Data? | Bibliographic Citation | Must Additional Data be Submitted? | Timeframe for Submission |
|---|---|---|---|---|---|---|
| §158.170(a) Product Analysis for Microbial Pesticides[1] | | | | | | |
| 151A-26 Physical and Chemical Properties: Storage stability | EP | ALL | NO | N/A | Yes 2/ | 15 months |

1/ Those end use products that do not use a manufacturing use product in their formulation must be supported by the product chemistry data requirements listed in Tables A and B.

2/ A storage stability study determining concentrations of beta-exotoxin must be determined in each EP immediately prior to packaging and 6 months later (unless a sooner or later interval can be demonstrated to be a more typical storage period). The fly larva bioassay as well as a specific confirmatory method, such as HPLC, must both be used for analysis. The Agency suspects that beta-exotoxin may be formed in certain end-use products subsequent to formulation.

# II. LABELING APPENDICES

SUMMARY-1

## LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

| Size of Label on Front Panel in Square Inches | Signal Word Minimum Type Size All Capitals | "Keep Out of Reach of Children" Minimum Type Size |
|---|---|---|
| 5 and under | 6 point | 6 point |
| above 5 to 10 | 10 point | 6 point |
| above 10 to 15 | 12 point | 8 point |
| above 15 to 30 | 14 point | 10 point |
| over 30 | 18 point | 12 point |

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

## COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 1 | Product name | All products | Front panel | Center front panel | |
| 2 | Company name and address | All products | None | Bottom front panel or end of label text | If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc. |
| 3 | Net contents | All products | None | Bottom front panel or end of label text | May be in metric units in addition to U.S. units. |
| 4 | EPA Reg. No. | All products | None | Front panel | Must be in similar type size and run parallel to other type. |
| 5 | EPA Est. No. | All products | None | Front panel immediately before or following Reg. No. | May appear on the container instead of the label. |
| 6A | Ingredients statement | All products | Front panel | Immediately following product name | Text must run parallel with other text on the panel. |
| 6B | Pounds/gallon statement | Liquid products where dosage is given as lbs. ai/unit area | Front panel | Directly below the main ingredients statement | |
| 7 | Front panel precautionary statements | All products | Front panel | | All front panel precautionary statements must be grouped together, preferably blocked. |
| 7A | Keep Out of Reach of Children (Child hazard warning) | All products | Front panel | Above signal word | Note type size requirements. |
| 7B | Signal word | All products | Front panel | Immediately below child hazard warning | Note type size requirements. |

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 7C | Skull & crossbones and word POISON (in red) | All products which are Category I based on oral, dermal, or inhalation toxicity | Front panel | Both in close proximity to signal word | |
| 7D | Statement of Practical Treatment or First Aid | All products in Categories I, II, and III | Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements. | Front panel for all | |
| 7E | Referral statement | All products where precautionary labeling appears on other than front panel | Front panel | | |
| 8 | Side/back panel precautionary statements | All products | None | Top or side of back panel preceding directions for use | Must be grouped under headings in 8A, 8B, and 8C; preferably blocked. |
| 8A | Hazards to humans and domestic animals | All products in Categories I, II, and III | None | Same as above | Must be preceded by appropriate signal word. |
| 8B | Environmental hazards | All products | None | Same as above | Environmental hazards include bee caution where applicable. |

SUMMARY-9

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 8C | Physical or chemical hazards | All pressurized products, others with flash points under 150°F | None | Same as above | Refer to Appendix II guide PHYS/CHEM |
| 9A | Restricted block | All restricted products | Top center of front panel | Preferably blocked | Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word. |
| 9B | Misuse statement | All products | Immediately following heading of directions for use | | Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." |
| 10A | Reentry statement | PR Notice 83-2 or as determined by the Agency | In the directions for use | Immediately after misuse statement | |
| 10B | Storage and disposal block | All products | In the directions for use | Immediately before specific directions for use or at the end of directions for use | Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements. |
| 10C | Directions for use | All products | None | None | May be in metric as well as U.S. units |

# PESTICIDE LABELING REQUIREMENTS
## 40 CFR 156.10

156.10

§ [redacted] Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as pre-

scribed in paragraph (b) of this section.

(iii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section.

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6 point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of

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registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(i) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight to weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22 25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

| Hazard indicators | Toxicity categories | | | |
|---|---|---|---|---|
| | I | II | III | IV |
| Oral $LD_{50}$ | Up to and including 50 mg/kg | From 50 thru 500 mg/kg | From 500 thru 5000 mg/kg | Greater than 5000 mg/kg |
| Inhalation $LC_{50}$ | Up to and including 2 mg/liter | From 2 thru 2 mg/liter | From 2 thru 20 mg/liter | Greater than 20 mg/liter |
| Dermal $LD_{50}$ | Up to and including 200 mg/kg | From 200 thru 2000 | From 2 000 thru 20 000 | Greater than 20 000 |
| Eye effects | Corrosive, corneal opacity not reversible within 7 days | Corneal opacity reversible within 7 days; irritation persisting for 7 days | No corneal opacity; irritation reversible within 7 days | No irritation |
| Skin effects | Corrosive | Severe irritation at 72 hours | Moderate irritation at 72 hours | Mild or slight irritation at 72 hours |

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A

statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (b)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (b)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

| Size of label front panel in square inches | Points | |
|---|---|---|
| | Required signal word "all capitals" | Keep out of reach of children |
| 5 and under | 6 | 6 |
| Above 5 to 10 | 10 | 6 |
| Above 10 to 15 | 12 | 8 |
| Above 15 to 30 | 14 | 10 |
| Over 30 | 18 | 12 |

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

| Toxicity category | Precautionary statements by toxicity category | |
|---|---|---|
| | Oral, inhalation, or dermal toxicity | Skin and eye local effects |
| I | Fatal if swallowed. If swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.] | Corrosive. Causes eye and skin damage. For skin exposure: Do not get on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.] |
| II | May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get on eyes, on skin, or on clothing. [Appropriate first aid statements required.] | Causes eye [and skin] irritation. Do not get in eyes on skin or on clothing. Harmful if swallowed. [Appropriate first aid statement required.] |
| III | Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.] | Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists. |
| IV | [No precautionary statements required.] | [No precautionary statements required.] |

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral $LD_{50}$ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute $LC_{50}$ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral $LD_{50}$ of 100 mg/kg or less, or a subacute dietary $LC_{50}$ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

| Flash point | Required text |
|---|---|
| (A) Pressurized Containers | |
| Flash point at or below 20° F. if there is a flashback at any valve opening | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame | Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| All other pressurized containers | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| (B) Nonpressurized Containers | |
| At or below 20° F | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| Above 20° F and not over 80° F | Flammable. Keep away from heat and open flame. |
| Above 80° F and not over 150° F | Do not use or store near heat or open flame. |

(i) *Directions for Use—(1) General requirements—(i) Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular;" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use—(A)* Detailed direc-

tions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes.

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved,

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

## PHYSICAL-CHEMICAL HAZARDS

| Criteria | Required Label Statement |
|---|---|
| I. Pressurized Containers | |
| A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening. | Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| C. ALL OTHER PRESSURIZED CONTAINERS | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| II. Non-Pressurized Containers | |
| A. Flashpoint at or below 20°F. | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| B. Flashpoint above 20°F and not over 80°F. | Flammable. keep away from heat and open flame. |
| C. Flashpoint over 80°F and not over 150°F. | Do not use or store near heat and open flame. |
| D. Flashpoint above 150°F. | None required. |

# STORAGE INSTRUCTIONS FOR PESTICIDES

## Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

## Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

## PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

## CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container dis instructions appropriate to the type of container.

1. Domestic use products must bear one of the follo container disposal statements:

| Container Type | Statement |
|---|---|
| Non-aerosol products (bottles, cans, jars) | Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash. |
| Non-aerosol products (bags) | Do not reuse bag. Discard bag in trash. |
| Aerosol products | Replace cap and discard containers in trash. Do not incinerate or puncture. |

2. All other products must bear container disposal instructions, based on container type, listed below:

| Container Type | Statement |
|---|---|
| Metal containers (non-aerosol) | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. |
| Glass containers | Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures. |
| Fiber drums with liners | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner. |
| Paper and plastic bags | Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Compressed gas cylinders | Return empty cylinder for reuse (or similar wording). |

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

# III. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

| FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET | EPA REGISTRATION NO |
|---|---|
| PRODUCT NAME | |
| APPLICANT'S NAME | DATE GUIDANCE DOCUMENT ISSUED |

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

| REGISTRANT'S AUTHORIZED REPRESENTATIVE | SIGNATURE | DATE |
|---|---|---|
| | | |

OMB Approval No. 2070-005
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:_____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated_____ on file with EPA is complete. current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:_____
(Signature

Dated: _____ _____
(Typed)

EPA Form 8570-3

| EPA | US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report** | Registration Standard for: | EPA Registration Number | | Form Approved OMB #2070-0057 Expires 11-30-89 |
|---|---|---|---|---|---|
| Registration Guideline No. | Name of Test | Testing not required for my product listed above *(Check below)* | I am complying with Data Requirements by - Citing MR ID No. | Submitting Data *(Attached)* *(Check below)* | (For EPA Use Only) Accession numbers assigned |
| Sec. 158.120 Product Chemistry | | | | | |
| 61-1 | Identity of ingredients | | | | |
| 61-2 | Statement of composition | | | | |
| 61-3 | Discussion of formation of ingredients | | | | |
| 62-1 | Preliminary analysis | | | | |
| 62-2 | Certification of limits | | | | |
| 62-3 | Analytical methods for enforcement limits | | | | |
| 63-2 | Color | | | | |
| 63-3 | Physical state | | | | |
| 63-4 | Odor | | | | |
| 63-5 | Melting point | | | | |
| 63-6 | Boiling point | | | | |
| 63-7 | Density, bulk-density, or specific gravity | | | | |
| 63-8 | Solubility | | | | |
| 63-9 | Vapor pressure | | | | |
| 63-10 | Dissociation constant | | | | |
| 63-11 | Octanol/water partition coefficient | | | | |
| 63-12 | pH | | | | |
| 63-13 | Stability | | | | |
| 63-14 | Oxidizing/reducing reaction | | | | |
| 63-15 | Flammability | | | | |
| 63-16 | Explodability | | | | |
| 63-17 | Storage stability | | | | |
| 63-18 | Viscosity | | | | |
| 63-19 | Miscibility | | | | |
| 63-20 | Corrosion Characteristics | | | | |
| 63-21 | Dielectric breakdown voltage | | | | |
| Sec. 158.135 Toxicology | | | | | |
| 81-1 | Acute oral toxicity, rat | | | | |
| 81-2 | Acute dermal toxicity, rabbit | | | | |
| 81-3 | Acute inhalation toxicity, rat | | | | |
| 81-4 | Primary eye irritation, rabbit | | | | |
| 81-5 | Primary dermal irritation | | | | |
| 81-6 | Dermal sensitization | | | | |

**Certification**

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| Typed Name and Title | Signature | Date |
|---|---|---|
| | | |

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

**CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA**

*(To qualify, certify ALL four items)*

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

| NAME OF FIRM | EPA COMPANY NUMBER |
|---|---|
| | |
| | |
| | |
| | |

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

| NAME OF FIRM | DATE OF OFFER |
|---|---|
| | |
| | |
| | |
| | |

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

| TYPED NAME | SIGNATURE | DATE |
|---|---|---|
| | | |